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EXAMINER
RAMIREZ, DELIA M

ART UNIT	PAPER NUMBER
1652	9

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/753,752	SHORT, JAY M.	
	Examiner	Art Unit	
	Delia M. Ramirez	1652	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-3 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 1-3 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on 02 January 2001 is/are: a)☐ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☒ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 7 and 8 .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Status of the Application

Claims 1-3 are pending.

Applicant's preliminary amendment in Paper No. 6, filed on 1/2/2001 is acknowledged.

Specification

1. The use of the trademarks has been noted throughout this application. See, for example, "Epicentre", "Amicon", "Boehringer-Mannheim", etc. They should be capitalized wherever they appear and be accompanied by the generic terminology.

Although the use of trademarks is permissible in patent applications, the proprietary nature of the trademarks should be respected and every effort made to prevent their use in any manner which might adversely affect their validity as trademarks.

Priority

2. Acknowledgment is made of a claim for foreign priority under 35 U.S.C. 119(a)-(d) to PCT/US96/11854 filed on 07/17/1996.

3. Acknowledgment is made of a claim for domestic priority under 35 U.S.C. 120 or 121 to US application No. 08/983,367 filed on 09/30/1998, 08/657,409 filed on 06/03/1996, 08/568,994 filed on 12/07/1995, and 08/503,606 filed on 07/18/1995.

Information Disclosure Statement

4. The information disclosure statement (IDS) submitted on 7/23/2002 was filed before the mailing date of the first Office Action on the merits. The submission is in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement is being considered by the examiner.

Drawings

5. The drawings have been reviewed and are objected under 37 CFR 1.84 or 1.152. See attached Notice of Draftsperson's Patent Drawing Review. Applicant is required to submit the drawing corrections within the time period set in the attached Office communication. See 37 CFR 1.85(a). Failure to take corrective action within the set period will result in ABANDOMENT of the application. In addition, if amendments to the specification are needed due to drawing corrections, Applicant is requested to submit such amendments while the case is being prosecuted to expedite the processing of the application.

Claim Rejections - 35 USC § 112, Second Paragraph

6. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

7. Claims 2 and 3 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

8. Claim 2 is indefinite in the recitation of "optionally" as it is unclear if the limitation following the term is part of the claimed invention. If the DNA in claim 2 is not modified or mutagenized, claim 2 is not further limiting claim 1. For examination purposes, the term "optionally" has not been given patentable weight. Correction is required.

9. Claim 3 is indefinite in the recitation of "process of screening clones having DNA ....for a specified protein characteristic" as it is confusing. As written, it is unclear how a clone, which is an organism containing a specific DNA fragment, can display a protein characteristic. It is suggested that the claim be amended to recite "process of screening clones having DNA... which express a protein with a specified characteristic..." or similar. For examination purposes, the suggested language will be used in the interpretation of the claim. Correction is required.

Claim Rejections - 35 USC § 112, First Paragraph

10. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

11. Claims 1-3 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claims 1-3 are directed to a method for identifying clones from a DNA library produced from an uncultivated organism wherein said clones express genera of proteins of any function and characteristic. While the specification discloses a method for identifying E. coli clones

comprising DNA isolated from a picoplankton sample wherein said clones express enzymes having hydrolase activity which are active after heating to 70 C for 45 minutes, there is no disclosure of how one can use the claimed method to isolate clones expressing proteins of other functions. While the specification discloses that the method can be used to detect pH stability, temperature stability, and substrate specificity, there is no disclosure of other detectable characteristics which are associated with proteins of other functions (i.e. non-hydrolases or non-enzymes). Furthermore, if the expression of a protein of a specific function is detected, there is no disclosure of how one can differentiate if the expression detected is due to expression of a DNA endogenous to the host cell (clone) or DNA isolated from the uncultured organism. As such, there is no disclosure of how one can distinguish between false positives and real positives. While the specification discloses heating the cell sample to 70 C for 45 minutes to kill the E. coli cell and inactivate those enzymes endogenous to E. coli, in some cases such procedure may also inactivate the protein which is the target for detection. The specification only discloses a single species of the genera of proteins which is insufficient to put one of ordinary skill in the art in possession of all attributes and features of the claimed method. Thus, one skilled in the art cannot reasonably conclude that Applicant had possession of the claimed invention at the time the instant application was filed.

12. Claims 1-3 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method for identifying E. coli clones of a recombinant DNA library derived from an uncultivated microorganism wherein the clones are screened for hydrolase activity after heating to 70 C, does not reasonably provide enablement for a method for

identifying clones of a recombinant DNA library derived from an uncultivated microorganism wherein the clones are tested for expression of a protein of any function or any characteristic. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

The criteria for undue experimentation, summarized in *re Wands*, 8, USPQ2nd 1400 (Fed. Cir. 1988) are: 1) quantity of experimentation necessary, 2) the amount of direction or guidance presented, 3) the presence and absence of working examples, 4) the nature of the invention, 5) the state of prior art, 6) the relative skill of those in the art, 7) the predictability or unpredictability of the art, and 8) the breath of the claims.

The scope of the claim is not commensurate with the enablement provided in regard to the infinite number of proteins and protein's characteristics encompassed by the claims. As indicated above, the specification discloses a method for identifying E. coli clones comprising DNA isolated from a picoplankton sample wherein said clones express enzymes having hydrolase activity which are active after heating to 70 C for 45 minutes, however, there is no disclosure of how one can use the claimed method to isolate clones expressing proteins of other functions or which are inactivated by heating to 70 C. While the specification discloses that the method can be used to detect pH, temperature stability, and substrate specificity, there is no disclosure of other detectable characteristics which are associated with proteins of other functions (i.e. non-hydrolases or non-enzymes). In addition, as indicated above, there is no disclosure of how one can distinguish between false and real positives since, with the exception of E. coli and hydrolases stable at more than 70 C, there is no teaching of how the expression of

a gene endogenous to the host cell (clone) and that of a gene isolated from the uncultivated organism can be differentiated if they both encode a protein of similar function. While the specification discloses heating the cell sample to 70 C for 45 minutes to kill the host cell and inactivate those enzymes endogenous to E. coli, in many cases such procedure will also inactivate the protein which is being detected. Therefore, due to the lack of relevant examples, the amount of information provided, the lack of knowledge about which other proteins and characteristics can be detected in the claimed method as well as how to distinguish false positives, one of ordinary skill in the art would have to go through the burden of undue experimentation in order to practice the full scope of the claimed method. Thus, Applicant has not provided sufficient guidance to enable one of ordinary skill in the art to make and use the invention in a manner reasonably correlated with the scope of the claims.

Claim Rejections - 35 USC § 103

13. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

14. Claims 1-3 are rejected under 35 U.S.C. 103(a) as being unpatentable over Yen et al. (US Patent No. 5171684, 1992) in view of More et al. (Appl. Environ. Microbiol. 60(5):1572-1580, 1994). Yen et al. teaches a process for identifying clones of a recombinant P. mendocina KR-1 library wherein the clones are screened in the liquid phase for toluene monooxygenase activity

using radioactive toluene (column 14, Example 11, Table I). The recombinant library of Yen et al. is not derived from an "uncultivated" microorganism. More et al. teaches the extraction of DNA from uncultivated microorganisms found in sediment. More et al. does not teach the screening of clones containing the DNA library isolated from uncultivated microorganisms in the liquid phase.

Claim 1 is directed to a method for identifying clones of a recombinant library produced from DNA of at least one uncultivated microorganism which comprises screening the expression products of such clones in the liquid phase. Claim 2 adds the limitation that the DNA is modified or mutagenized prior to its use in the recombinant library. Claim 3 is directed to a method for screening clones having DNA recovered from an uncultivated organism which express a protein with a specified characteristic wherein the DNA is optionally mutagenized before it is used to transform the clones.

In regard to claim 1, it would have been obvious to one of ordinary skill in the art at the time the invention was made to practice the method as taught by Yen et al. with a DNA library from uncultivated microorganisms from sediment as taught by More et al. A person of ordinary skill in the art is motivated to use a DNA library from uncultivated microorganisms from sediment for the benefit of identifying DNA genes encoding products with specific characteristics without having to first isolate a particular microorganism and also to circumvent the biases implicit in culture-based procedures, such as gene mutations as a result of the environmental conditions under which culturing takes place. One of ordinary skill in the art has a reasonable expectation of success at practicing the method of Yen et al. with a DNA library isolated from uncultivated microorganism since More et al. teaches the successful isolation of

microbial DNA from sediment. Therefore, the invention as a whole would have been prima facie obvious to a person of ordinary skill in the art at the time the invention was made.

In regard to claims 2 and 3, it would have been obvious to one of ordinary skill in the art at the time the invention was made to practice the method of Yen et al. and More et al. as describe above, with DNA which has been mutagenized prior to its use to transform the clones. A person of ordinary skill in the art is motivated to mutagenize the DNA before transforming the clones to study the effect of mutations in the function of the corresponding protein and to further characterize the structure-function relationship in that protein. One of ordinary skill in the art has a reasonable expectation of success at practicing the method of Yen et al. and More et al. since DNA mutagenesis is well known and widely used in the art. Therefore, the invention as a whole would have been prima facie obvious to a person of ordinary skill in the art at the time the invention was made.

Double Patenting

15. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

16. Claims 1-3 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-22 of U.S. Patent No. 6280926 in view of More et al. (Appl. Environ. Microbiol. 60(5):1572-1580, 1994). The teachings of More et al. have been discussed above. Claims 1-22 of U.S. Patent No. 6280926 are directed to a method for identifying clones which express proteins having enzymatic activity wherein the DNA derives from eukaryotic organisms which may or may not be uncultivated. Although the conflicting claims are not identical, they are not patentably distinct from each other for the following reasons.

Claims 1-3 of the instant application are directed to a method for identifying clones of a recombinant library produced from DNA derived from uncultivated organisms which comprises screening the expression products (any function) of such clones in any way or in the liquid phase, wherein the DNA can be modified or mutagenized prior to transformation of the clones.

As indicated previously, it would have been obvious to one of skill in the art at the time the invention was made to practice the method of claims 1-22 of U.S. Patent No. 6280926 with DNA isolated from uncultivated organisms and to mutagenized the DNA prior to its used in transforming host cells. A person of skill in the art is motivated to use a DNA library from uncultivated microorganisms for the benefit of identifying DNA genes encoding products with specific characteristics without having to first isolate a particular microorganism and also to circumvent the biases implicit in culture-based procedures, such as gene mutations as a result of the environmental conditions under which culturing takes place. Furthermore, one of skill in the art is motivated to mutagenize the DNA before transforming the clones to study the effect of mutations in the function of the corresponding protein and to further characterize the structure-

function relationship in that protein. One of skill in the art has a reasonable expectation of success at practicing the method claimed in US Patent No. 6280926 with DNA isolated from uncultivated organisms which is mutagenized prior to its use in transformation of the host cells (clones) since More et al. teaches the successful isolation of microbial DNA from sediment and mutagenesis of DNA is well known and widely used in the art. Therefore, the invention as a whole would have been prima facie obvious to a person of ordinary skill in the art at the time the invention was made.

17. Claims 1-3 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-9 of U.S. Patent No. 6168919 in view of More et al. (Appl. Environ. Microbiol. 60(5):1572-1580, 1994). The teachings of More et al. have been discussed above. Claims 1, 2, 4-8 of U.S. Patent No. 6168919 are directed to a method for identifying clones of a recombinant library wherein the DNA for the library is recovered from a plurality of microorganisms and wherein the clones are screened in the liquid phase. Claims 3 and 9 of U.S. Patent No. 6168919 add the limitation to claims 1 and 4, respectively, of the DNA in the clones encoding an enzyme. Although the conflicting claims are not identical, they are not patentably distinct from each other for the following reasons.

The subject matter of claims 1-3 of the instant application has been described above. As indicated previously, it would have been obvious to one of skill in the art at the time the invention was made to practice the method of claims 1, 2, 4-8 of U.S. Patent No. 6168919 with DNA isolated from uncultivated organisms and to mutagenized the DNA prior to its used in transforming host cells. A person of skill in the art is motivated to use a DNA library from

uncultivated microorganisms for the benefit of identifying DNA genes encoding products with specific characteristics without having to first isolate a particular microorganism and also to circumvent the biases implicit in culture-based procedures, such as gene mutations as a result of the environmental conditions under which culturing takes place. Furthermore, one of skill in the art is motivated to mutagenize the DNA before transforming the clones to study the effect of mutations in the function of the corresponding protein and to further characterize the structure-function relationship in that protein. One of skill in the art has a reasonable expectation of success at practicing the method claimed in US Patent No. 6168919 with DNA isolated from uncultivated organisms which is mutagenized prior to its use in transformation of the host cells (clones) since More et al. teaches the successful isolation of microbial DNA from sediment and mutagenesis of DNA is well known and widely used in the art. Therefore, the invention as a whole would have been prima facie obvious to a person of ordinary skill in the art at the time the invention was made.

18. Claims 1-3 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-15 of U.S. Patent No.5958672 in view of More et al. (Appl. Environ. Microbiol. 60(5):1572-1580, 1994). The teachings of More et al. have been discussed above. Claims 1-15 of U.S. Patent No.5958672 are directed to a method for identifying any protein activity, including enzymatic activity, by screening of host cells comprising DNA from any organism, cultured and uncultured. Although the conflicting claims are not identical, they are not patentably distinct from each other for the following reasons.

The subject matter of claims 1-3 of the instant application has been described above. As indicated previously, it would have been obvious to one of skill in the art at the time the invention was made to practice the method of claims 1-15 of U.S. Patent No.5958672 with DNA isolated from uncultivated organisms and to mutagenized the DNA prior to its used in transforming host cells. A person of skill in the art is motivated to use a DNA library from uncultivated microorganisms for the benefit of identifying DNA genes encoding products with specific characteristics without having to first isolate a particular microorganism and also to circumvent the biases implicit in culture-based procedures, such as gene mutations as a result of the environmental conditions under which culturing takes place. Furthermore, one of skill in the art is motivated to mutagenize the DNA before transforming the clones to study the effect of mutations in the function of the corresponding protein and to further characterize the structure-function relationship in that protein. One of skill in the art has a reasonable expectation of success at practicing the method claimed in US Patent No. 5958672 with DNA isolated from uncultivated organisms which is mutagenized prior to its use in transformation of the host cells (clones) since More et al. teaches the successful isolation of microbial DNA from sediment and mutagenesis of DNA is well known and widely used in the art. Therefore, the invention as a whole would have been prima facie obvious to a person of ordinary skill in the art at the time the invention was made.

19. Claims 1-3 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 32-47 of copending Application No. 09/421629 in view of More et al. (Appl. Environ. Microbiol. 60(5):1572-1580,

1994). The teachings of More et al. have been discussed above. Claims 32-47 are directed to a method of identifying a bioactivity or a biomolecule which comprises enzymes wherein the DNA derives from eukaryotic organisms which may or may not be uncultivated. Although the conflicting claims are not identical, they are not patentably distinct from each other for the following reasons.

The subject matter of claims 1-3 of the instant application has been described above. As indicated previously, it would have been obvious to one of skill in the art at the time the invention was made to practice the method of claims 32-47 of copending Application No. 09/421629 with DNA isolated from uncultivated organisms and to mutagenized the DNA prior to its used in transforming host cells. A person of skill in the art is motivated to use a DNA library from uncultivated microorganisms for the benefit of identifying DNA genes encoding products with specific characteristics without having to first isolate a particular microorganism and also to circumvent the biases implicit in culture-based procedures, such as gene mutations as a result of the environmental conditions under which culturing takes place. Furthermore, one of skill in the art is motivated to mutagenize the DNA before transforming the clones to study the effect of mutations in the function of the corresponding protein and to further characterize the structure-function relationship in that protein. One of skill in the art has a reasonable expectation of success at practicing the method of claims 32-47 of copending Application No. 09/421629 with DNA isolated from uncultivated organisms which is mutagenized prior to its use in transformation of the host cells (clones) since More et al. teaches the successful isolation of microbial DNA from sediment and mutagenesis of DNA is well known and widely used in the

art. Therefore, the invention as a whole would have been prima facie obvious to a person of ordinary skill in the art at the time the invention was made.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

20. Claims 1-3 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 11, 14 and 16 of copending Application No. 09/467740 in view of More et al. (Appl. Environ. Microbiol. 60(5):1572-1580, 1994). The teachings of More et al. have been discussed above. Claims 11, 14 and 16 of copending Application No. 09/467740 are directed to a method for identifying enzymatic activity by screening host cells which have been transformed with DNA from a plurality of organisms. Although the conflicting claims are not identical, they are not patentably distinct from each other for the following reasons.

The subject matter of claims 1-3 of the instant application has been described above. As indicated previously, it would have been obvious to one of skill in the art at the time the invention was made to practice the method of claims 11, 14 and 16 of copending Application No. 09/467740 with DNA isolated from uncultivated organisms and to mutagenized the DNA prior to its used in transforming host cells. A person of skill in the art is motivated to use a DNA library from uncultivated microorganisms for the benefit of identifying DNA genes encoding products with specific characteristics without having to first isolate a particular microorganism and also to circumvent the biases implicit in culture-based procedures, such as gene mutations as a result of the environmental conditions under which culturing takes place. Furthermore, one of

skill in the art is motivated to mutagenize the DNA before transforming the clones to study the effect of mutations in the function of the corresponding protein and to further characterize the structure-function relationship in that protein. One of skill in the art has a reasonable expectation of success at practicing the method of claims 11, 14 and 16 of copending Application No. 09/467740 with DNA isolated from uncultivated organisms which is mutagenized prior to its use in transformation of the host cells (clones) since More et al. teaches the successful isolation of microbial DNA from sediment and mutagenesis of DNA is well known and widely used in the art. Therefore, the invention as a whole would have been prima facie obvious to a person of ordinary skill in the art at the time the invention was made.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

21. Claims 1-3 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-20, 23-25, 27-28 of copending Application No. 09/713176 in view of More et al. (Appl. Environ. Microbiol. 60(5):1572-1580, 1994). The teachings of More et al. have been discussed above. Claims 1-20, 23-25, 27-28 of copending Application No. 09/713176 are drawn to a method for identifying any protein activity by screening the expression products of host cells transformed with a DNA library. Although the conflicting claims are not identical, they are not patentably distinct from each other for the following reasons.

The subject matter of claims 1-3 of the instant application has been described above. As indicated previously, it would have been obvious to one of skill in the art at the time the

invention was made to practice the method of claims 1-20, 23-25, 27-28 of copending Application No. 09/713176 with DNA isolated from uncultivated organisms and to mutagenized the DNA prior to its used in transforming host cells. A person of skill in the art is motivated to use a DNA library from uncultivated microorganisms for the benefit of identifying DNA genes encoding products with specific characteristics without having to first isolate a particular microorganism and also to circumvent the biases implicit in culture-based procedures, such as gene mutations as a result of the environmental conditions under which culturing takes place. Furthermore, one of skill in the art is motivated to mutagenize the DNA before transforming the clones to study the effect of mutations in the function of the corresponding protein and to further characterize the structure-function relationship in that protein. One of skill in the art has a reasonable expectation of success at practicing the method of claims 1-20, 23-25, 27-28 of copending Application No. 09/713176 with DNA isolated from uncultivated organisms which is mutagenized prior to its use in transformation of the host cells (clones) since More et al. teaches the successful isolation of microbial DNA from sediment and mutagenesis of DNA is well known and widely used in the art. Therefore, the invention as a whole would have been prima facie obvious to a person of ordinary skill in the art at the time the invention was made.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

22. Claims 1-3 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-5 of copending Application No. 09/861267 in view of More et al. (Appl. Environ. Microbiol. 60(5):1572-1580,

1994). The teachings of More et al. have been discussed above. Claims 1-5 of copending Application No. 09/861267 are directed to a method of screening clones for expression of a specific enzymatic activity wherein the DNA in such clones derived from any organism. Although the conflicting claims are not identical, they are not patentably distinct from each other for the following reasons.

23. The subject matter of claims 1-3 of the instant application has been described above. As indicated previously, it would have been obvious to one of skill in the art at the time the invention was made to practice the method of claims 1-5 of copending Application No. 09/861267 with DNA isolated from uncultivated organisms and to mutagenized the DNA prior to its used in transforming host cells. A person of skill in the art is motivated to use a DNA library from uncultivated microorganisms for the benefit of identifying DNA genes encoding products with specific characteristics without having to first isolate a particular microorganism and also to circumvent the biases implicit in culture-based procedures, such as gene mutations as a result of the environmental conditions under which culturing takes place. Furthermore, one of skill in the art is motivated to mutagenize the DNA before transforming the clones to study the effect of mutations in the function of the corresponding protein and to further characterize the structure-function relationship in that protein. One of skill in the art has a reasonable expectation of success at practicing the method of claims 1-5 of copending Application No. 09/861267 with DNA isolated from uncultivated organisms which is mutagenized prior to its use in transformation of the host cells (clones) since More et al. teaches the successful isolation of microbial DNA from sediment and mutagenesis of DNA is well known and widely used in the

art. Therefore, the invention as a whole would have been prima facie obvious to a person of ordinary skill in the art at the time the invention was made.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

24. Claims 1-3 provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-22 of copending Application No. 09/875412 in view of More et al. (Appl. Environ. Microbiol. 60(5):1572-1580, 1994). The teachings of More et al. have been discussed above. Claims 1-22 of copending Application No. 09/875412 are directed to a method for identifying clones which express proteins having enzymatic activity wherein the DNA derives from eukaryotic organisms which may or may not be uncultivated. Although the conflicting claims are not identical, they are not patentably distinct from each other for the following reasons.

The subject matter of claims 1-3 of the instant application has been described above. As indicated previously, it would have been obvious to one of skill in the art at the time the invention was made to practice the method of claims 1-22 of copending Application No. 09/875412 with DNA isolated from uncultivated organisms and to mutagenized the DNA prior to its used in transforming host cells. A person of skill in the art is motivated to use a DNA library from uncultivated microorganisms for the benefit of identifying DNA genes encoding products with specific characteristics without having to first isolate a particular microorganism and also to circumvent the biases implicit in culture-based procedures, such as gene mutations as a result of the environmental conditions under which culturing takes place. Furthermore, one of

skill in the art is motivated to mutagenize the DNA before transforming the clones to study the effect of mutations in the function of the corresponding protein and to further characterize the structure-function relationship in that protein. One of skill in the art has a reasonable expectation of success at practicing the method of claims 1-22 of copending Application No. 09/875412 with DNA isolated from uncultivated organisms which is mutagenized prior to its use in transformation of the host cells (clones) since More et al. teaches the successful isolation of microbial DNA from sediment and mutagenesis of DNA is well known and widely used in the art. Therefore, the invention as a whole would have been prima facie obvious to a person of ordinary skill in the art at the time the invention was made.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Conclusion

25. No claim is in condition for allowance.

26. It is noted that if the references cited by the Examiner are too long, only relevant pages will be enclosed with the instant Action.

27. Applicants are requested to submit a clean copy of the pending claims (including amendments, if any) in future written communications to aid in the examination of this application.

28. Certain papers related to this application may be submitted to Art Unit 1652 by facsimile transmission. The FAX number is (703) 308-4556. The faxing of such papers must conform with the notices published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94

(December 28, 1993) (see 37 CFR 1.6(d)). NOTE: If Applicant submits a paper by FAX, the original copy should be retained by Applicant or Applicant's representative. NO DUPLICATE COPIES SHOULD BE SUBMITTED, so as to avoid the processing of duplicate papers in the Office.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Delia M. Ramirez whose telephone number is (703) 306-0288. The examiner can normally be reached on Monday-Friday from 8:30 AM to 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Ponnathapura Achutamurthy can be reached on (703) 308-3804. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Delia M. Ramirez, Ph.D.
Patent Examiner
Art Unit 1652

DR
December 19, 2002

REBECCA E. PRUTY
PRIMARY EXAMINER
GROUP ~~1800~~ 1600